UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF IOWA

THE UNITED STATES OF AMERICA, the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, and the DISTRICT OF COLUMBIA, *ex rel.* JAMES ARCILESI,

Plaintiffs,

v.

BAUSCH HEALTH COMPANIES INC., BAUSCH HEALTH US, LLC, BAUSCH HEALTH AMERICAS, INC., WILLIAM HUMPHRIES, STEVE KREIDER, MICHAEL MCMYNE, KELLY WEBBER, and AIMEE DUBINSKI,

Defendants.

QUI TAM COMPLAINT
AND
DEMAND FOR A JURY TRIAL

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. §§ 3729 *et seq.*

Civil Action No.

19-CV-139-LRR

1. Relator James Arcilesi ("Relator") brings this qui tam action on behalf of the United States of America ("United States"), the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington (collectively "States"), and the District of Columbia, by and through his undersigned attorneys Thomas & Solomon LLP, and alleges as follows:

INTRODUCTION

2. This is a civil fraud action by qui tam Relator on behalf of the United States, the States, and the District of Columbia, against Bausch Health Companies Inc., Bausch Health US, LLC, Bausch Health Americas, Inc., William Humphries, Steve Kreider, Michael McMyne, Kelly Webber, and Aimee Dubinski (collectively "Valeant" or "Defendants") to recover treble damages and civil penalties under the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and each of the States' and the District of Columbia's counterparts, as well as the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), for damages sustained by Medicare, Medicaid, TRICARE, and the other federal and state government healthcare programs identified below.

3. Relator is aware that Valeant's fraudulent conduct occurred on a national level.

4. During the relevant time period, Valeant knowingly engaged in unlawful promotion of prescription drugs and paid illegal remuneration to physicians to induce prescriptions of Valeant drugs at the national level.

5. The government healthcare programs operate on the assumption that a physician is exercising his or her independent professional judgment and always in the best health interest of a patient when deciding whether to prescribe a certain prescription drug for a patient.

6. Valeant undermined that tenet of the government healthcare programs by promoting prescription drugs throughout the United State for off-label uses not approved by the Food and Drug Administration, which directly jeopardizes and endangers patient safety.

7. Additionally, Valeant undermined the FDA's Risk Evaluation and Mitigation

Strategy program requirements by withholding critical safety information of Valeant drugs, which further jeopardized patient safety.

8. Valeant further undermined that independent medical judgment and patient safety by providing kickbacks to physicians throughout the United States to induce prescriptions of Valeant's drugs that the physician would otherwise not prescribe.

9. As a result of Valeant's fraudulent schemes, Valeant caused to be submitted false claims for payment to the government health programs described herein, which caused Medicare, Medicaid, and the other healthcare programs, to pay for prescriptions that were off-label, tainted, and otherwise ineligible for reimbursement, and that otherwise would not have been presented for payment to the government programs.

PARTIES

10. Relator James Arcilesi was employed as a sales representative in the Virginia, Maryland, and District of Columbia area for Valeant in its dermatology division, Ortho Dermatologics, from approximately December 2014 until he was constructively discharged in April 2019.

11. During his time at Valeant, Relator sold and was trained on a variety of drugs including Siliq, Bryhali, Jublia, Duobrii, Retin-A Micro, and Onexton.

12. Defendant Bausch Health Companies Inc. (f/k/a Valeant Pharmaceuticals International, Inc.) is a global manufacturer of branded and generic pharmaceuticals with a diversified portfolio of products in segments such as eye health (Bausch + Lomb division), gastrointestinal diseases (Salix Pharmaceuticals division), and, relevant here, dermatology (Ortho Dermatologics division).

13. Defendant Bausch Health US, LLC (f/k/a Valeant Pharmaceuticals North

America LLC) is a wholly owned subsidiary of Bausch Health Companies Inc. involved in the distribution and marketing of Valeant pharmaceutical drugs.

14. Defendant Bausch Health Americas, Inc. (f/k/a Valeant Pharmaceuticals International) is a wholly owned subsidiary of Bausch Health Companies Inc.

15. Defendant William ("Bill") Humphries is the President of the Ortho Dermatologics division of Valeant.

16. Defendant Humphries had knowledge of Valeant's fraudulent practices as raised by Relator to Mr. Humphries and no action was taken.

17. Defendant Steve Kreider is the Vice President of Sales of the Ortho Dermatologics division of Valeant.

18. Defendant Kreider had knowledge of Valeant's fraudulent practices as raised by Relator to Mr. Kreider and no action was taken.

19. Defendant Michael McMyne was a former Vice President of Sales of the Ortho Dermatologics division of Valeant.

20. Upon information and belief, Defendant McMyne developed Valeant sales policies and had knowledge of Valeant's fraudulent practices.

21. Defendant Kelly Webber is the Senior Vice President and Chief Human Resources Officer of Valeant.

22. Defendant Webber had knowledge of Valeant's fraudulent practices as raised by Relator to Ms. Webber and no action was taken.

23. Defendant Aimee Dubinski is the Director of Human Resources for Valeant.

24. Defendant Dubinski had knowledge of Valeant's fraudulent practices as raised by Relator to Ms. Dubinski and no action was taken.

JURISDICTION AND VENUE

25. This action arises under the Federal False Claims Act ("FCA"), as amended, 31 U.S.C. §§ 3729-33.

26. This Court has subject matter jurisdiction over this action under 31 U.S.C. § 3730, 3732(a) and 28 U.S.C. §§ 1331, 1345.

27. This Court has personal jurisdiction over Defendants because Defendants transact business in the Northern District of Iowa. *See* 31 U.S.C. § 3732(a) ("Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred.").

28. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b), (c)(2).

FACTUAL BACKGROUND

The False Claims Act

29. The False Claims Act ("FCA") provides that a person is liable to the United States Government for each instance in which the person knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1)(A).

30. The False Claims Act also provides that a person is liable who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," as well as any person who "conspires to commit a violation of [the False Claims Act]." 31 U.S.C. § 3729(a)(1)(B), (C).

31. The FCA defines "knowingly" to mean a person that "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information;

or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

32. The FCA permits any person having information pertaining to a false or fraudulent claim for payment from Government funds to bring an action for herself, as the Relator, and for the Government to allow her to share in any recovery.

33. The FCA provides that no proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1)(B).

34. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim for payment or approval is liable for a civil penalty of not less than $5,000 and not more than a maximum statutory amount as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461), plus three times the amount of the damages sustained by the government. 31 U.S.C. §§ 3729(a)(1).

35. Twenty-nine states and the District of Columbia have enacted analogous false claims act statutes that apply to Medicaid fraud (the "State False Claims Acts").

Applicable Federal Government Healthcare Programs

36. The United States Government, through Medicare and Medicaid, and the Plaintiff States, through Medicaid, reimburse a large percentage of all drug prescriptions.

37. Private insurers also reimburse drug prescriptions.

38. While each government healthcare program establishes its own reimbursement criteria, none knowingly pays for medications that are not prescribed for a medically accepted indication or that are prescribed as a result of false or misleading information disseminated by pharmaceutical manufacturers to either payors or healthcare providers.

39. In addition, none of the government-funded healthcare programs willingly pay

for drugs that were prescribed as the result of the pharmaceutical manufacturer's unlawful inducements or unlawful marketing activities.

Medicare

40. Medicare is a federal health program that provides federal subsidized health insurance primarily for persons who are 65 or older or disabled. See 42 U.S.C. §§ 1395, *et seq*. ("Medicare Program" or "Medicare").

41. There are four parts to Medicare: Part A (hospital insurance); Part B (medical insurance); Part C (Medicare Advantage); and Part D (prescription drug coverage).

42. Medicare Part A generally pays for inpatient services for eligible beneficiaries in hospitals, hospices, and skilled nursing facilities, as well as some home healthcare services. 42 U.S.C. §§ 1395e, 1395i-5.

43. Prescription drugs are covered under Medicare Part A only if they are administered on an inpatient basis in a hospital or similar setting.

44. Medicare Part B covers some healthcare services and products not covered by Part A, generally on an outpatient basis.

45. Doctor's visits and other services are covered by Part B.

46. Medicare Part B also pays for some types of prescription drugs that are not administered in a hospital setting, which typically include drugs administered by a physician or other provider in an outpatient setting, including some anticancer drugs. 42 U.S.C. §§ 1395k(a), 1395x(s)(2); 42 C.F.R. § 405.517.

47. Medicare Part C, in effect, combines Parts A and B, but differs in that it is supplied through private insurance companies.

48. Medicare beneficiaries have the option to receive their Medicare benefits

through private health insurance plans instead of through the original Medicare plan (Parts A and B).

49. Medicare Part D began subsidizing optional prescription drug coverage for all beneficiaries on January 1, 2006.

50. This drug benefit covers drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k).

51. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D.

52. The Department of Health and Human Services ("HHS"), through its component agency, The Centers for Medicare & Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans.

53. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts.

54. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

55. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient takes the prescription to a pharmacy to be filled.

56. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM").

57. The pharmacy receives reimbursement from the sponsor (or PBM) for the "gross drug cost" of the drug dispensed, the portion of the drug cost not paid by the beneficiary, the pharmacy's dispensing fee, and any applicable sales taxes.

58. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data elements regarding the prescription claim such as the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

59. Payments to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322.

60. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. *See* CMS Updated Instructions: Requirements for Submitting Prescription Drug Event Data, 4.27.2006, pg. 9.

61. PDE records are an integral part of the process that enables CMS to administer the Part D benefit.

62. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

63. Medicare Part D only covers drugs that are used for a medically accepted indication, which means a use that is approved under the Food, Drug, and Cosmetics Act ("FDCA"), or a use which is supported by one or more citations included or approved for inclusion in one of the specified drug compendia. 42 U.S.C. § 1395w-102(e)(1) & (e)(4); 42 U.S.C. § 1396r-8(g)(1)(B)(i), (k)(6); 42 C.F.R. § 423.100.

64. Part D Plan Sponsors are only authorized to approve payment for prescription drugs for Medicare Part D beneficiaries if the drug is prescribed for a medically accepted indication, as defined above.

Medicaid

65. Medicaid is a joint program of the United States and state governments to provide medical services, including prescription drugs, to persons who could not otherwise afford them.

66. More prescription drugs are purchased through the Medicaid program than through any other insurance program in the United States.

67. All of the States and the District of Columbia participate in Medicaid and use State or District funds blended with federal funds for the purchase of pharmaceutical drugs.

68. Medicaid pays for services pursuant to plans developed by the states and approved by HHS through CMS. 42 U.S.C. §§ 1396a(a)-(b).

69. After the States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to rates the states establish, the federal government then pays each State a statutorily-established share of "the total amount expended . . . as medical assistance under the State plan." *See* 42 U.S.C. §§ 1396b(a)(1), 1396b(a)(1), 1903(a)(1).

70. This federal-to-state payment is known as federal financial participation ("FFP").

71. The majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients.

72. Typically, after processing the claims, these private companies then generate

funding requests to the state Medicaid programs.

73. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter.

74. CMS then reviews and adjusts the quarterly estimate as necessary and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter.

75. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment.

76. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimate expenditures to actual expenditures). 42 C.F.R. § 430.30.

77. Although Medicaid is administered on a stated-by-state basis, the state programs adhere to federal guidelines.

78. As such, federal statutes and regulations restrict the prescription drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs.

79. For example, like Medicare, prescription drugs under Medicaid are limited to "covered outpatient drugs" that are used for "a medically accepted indication." 42 U.S.C. § 1396b(i)(10), 1396r-8(k)(2), (3).

80. Thus, like Medicare, Medicaid only covers drugs that are used for a medically accepted indication, i.e. on-label.

81. Additionally, claims arising from illegal kickbacks are also not authorized to be paid under state regulatory regimes.

82. For example, the New York regulatory regime provides that an "overpayment

includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake." N.Y. Comp. Codes R. & Regs. Title 18 § 518.1(c).

83. "Unacceptable practice" is defined to include "[b]ribes and kickbacks," *Id.* § 515.2(b)(5), and lists within this category both "soliciting and receiving," *Id.* § 515.2(b)(5)(ii), and "offering or paying," *Id.* § 515.2(b)(5)(iv), "either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program," *Id.* §515.2(b)(5)(ii), (iv).

84. New York's anti-kickback statute forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law §§ 366-d-f.

85. Providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS.

86. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

87. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

88. In New York, for example, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that

claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished," "will be subject to the following certification. . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

CHAMPUS/TRICARE

89. TRICARE (formerly CHAMPUS) is the healthcare system of the United States military, designed to maintain the health of active duty service personnel, provide healthcare during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and certain military retirees and their dependents.

90. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian healthcare providers.

91. Five managed care support contractors create networks of civilian healthcare providers.

CHAMPVA

92. CHAMPVA is a health care program administered by the United States Department of Veterans Affairs ("VA") for families of veterans with 100 percent service-connected disability.

Federal Employees Health Benefits Program

93. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and their dependents.

94. FEHBP is a collection of individual healthcare plans such as the Blue Cross and Blue Shield Association.

95. FEHBP plans are managed by the Office of Personnel Management.

Statutory and Regulatory Provisions Applicable to Valeant's False Claims Act Violations

96. The United States Food and Drug Administration ("FDA") regulates drugs based on the "intended uses" for such products.

97. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a), 360b(a).

98. The FDA approval process is extremely expensive for pharmaceutical manufacturers.

99. As a result, pharmaceutical companies typically seek approval of a drug for limited indications.

100. The FDA reviews pharmaceutical manufacturers' New Drug Applications ("NDAs") to determine whether the drugs are safe and effective for each intended use. *See* 21 U.S.C. § 355.

101. Once a drug is approved for a particular use (or indication), doctors may legally prescribe the drug for any "non-indicated" or off-label purpose.

102. Doctors may also independently request information from drug manufacturers about such off-label uses with few exceptions.

103. The FDA prohibits, however, drug manufacturers from marketing or promoting drugs for uses, i.e., indications, not explicitly approved by the FDA.

104. More specifically, "off-label marketing" refers to the marketing of an FDA approved drug for uses that have not undergone FDA scrutiny and approval.

105. Under the statute, qualified medical professionals may provide purely scientific medical information for uses other than those approved by the FDA; all other presentations,

promotions and marketing to physicians for uses other than those approved by the FDA are considered off-label marketing or "misbranding" proscribed by the Food, Drug and Cosmetics Act ("FDCA"). *See* 21 U.S.C. §§ 331(a)-(b), 352(a), (f).

106. This includes any attempts by a pharmaceutical sales representative to initiate discussions with, or solicit questions from, physicians concerning off-label use.

107. Strong policy reasons exist for strict regulation of off-label marketing.

108. Off-label promotion bypasses the FDA's strict review and approval process.

109. It also removes the incentive to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity for its use.

110. Pursuant to the FDCA, 21 U.S.C. § 301, et seq., the FDA strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved prescription drugs.

111. FDA interprets "labeling" in its regulations broadly to include items that are "descriptive of a drug[;]" "supplied by the manufacturer" or its agents; and intended for "use by medical [personnel.]" 21 C.F.R. § 202.1.

112. The FDCA defines both misleading statements and the omission of material facts in a label or product labeling as "misbranding." 21 U.S.C. § 321(n).

113. Labeling includes brochures, booklets, detailing pieces, literature, medical reprints, sound recordings, exhibits and audio visual material. 21 C.F.R. § 202.1(l)(2).

114. The FDA regulations deem "advertising" to include any media-based activities that appear in magazines, newspapers, professional journals and on television, radio, and telephone communications systems. See 21 C.F.R. § 202.1(1)(1).

115. Courts have consistently held that oral statements made by a company's sales

representative relating to a pharmaceutical product constitute commercial advertising or promotion. *See, e.g.*, *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 10 (7th Cir. 1992) (interpreting the Lanham Act).

116. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading "misbrand" a drug in violation of the FDCA, 21 U.S.C. §§ 301, 321, 331, 352, 360b, 371; 21 C.F.R. §§ 202.1(e)(6), (e)(7); 21 C.F.R. § 1.21.

117. Such violations exist where promotional and marketing materials and presentations for an FDA approved drug: (1) minimize, understate, or misrepresent the risks, contra-indications, and complications associated with that drug; (2) overstate or misrepresent the risks, contra-indications, and complications associated with any competing drugs; (3) reference "off-label" uses of the drug — i.e., those uses that have not been approved by the FDA — or expressly or implicitly promote uses and/or dosing regimens for which the drug is not indicated; (4) fail to reveal facts material in light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement; (5) contain representations or suggestions, not approved or permitted in the labeling, that is not demonstrated by substantial evidence or substantial clinical experience; (6) present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; (7) use a quote or paraphrase out of context to convey a false or misleading idea; or (8) are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or about any competing drug. See 21 C.F.R. §§ 202.1 (e)(4)(5)(6), (7).

118. Oral statements and written materials presented at industry-supported activities,

including lectures and teleconferences, provide evidence of a product's intended use.

119. If these statements or materials promote a use inconsistent with the product's FDA approved labeling, it is misbranded as it fails to provide adequate directions for all intended uses.

Medicare and Medicaid Coverage of Off-Label Prescriptions

120. By statute, Medicare and Medicaid can only reimburse claims for drugs if the drug is dispensed for a "medically accepted indication." *See e.g.*, 42 U.S.C. § 1369r-8(k).

121. The law further provides a drug is dispensed for a "medically accepted indication" if it is for a use that the FDA has approved. *See, e.g., id.*

122. Thus, normally, Medicare and Medicaid can only pay for pharmaceutical prescriptions if the doctor has prescribed the drug for a use that the FDA approved.

123. This makes sense as the FDA comprehensively reviews pharmaceutical manufacturers' detailed applications for new drugs to determine whether the drugs are safe and effective for each intended use. See 21 U.S.C. § 355.

124. Congress requires Medicare and Medicaid to only pay for prescription drugs that are safe and effective for their prescribed use.

125. However, there is an exception to Medicare and Medicaid's FDA approval requirement.

126. The law also considers it a "medically accepted indication," and thus permits Medicare and Medicaid to reimburse, if the prescribed use is "supported by citation" in one or more of several specified drug compendia. 42 U.S.C. § 1395x(t)(2)(B) and 42 U.S.C. § 1395w-102(2) (2007) (Medicare); 42 U.S.C. § 1396r-8(k)(6) and 42 U.S.C. § 1396r-8(g)(1)(B)(1) (Medicaid).

127. The drug compendia are privately owned, written and published indices of various pharmaceuticals products.

128. For each product, a compendia includes information about the product's pharmacologic and pharmacokinetic properties (such as adverse effects, and drug interactions) and the FDA-approved indications for that drug.

129. The compendia also, however, includes information about studies of the product in diseases not approved by the FDA and not listed on the label (i.e., "off-label" uses).

130. Under Medicare Part B, until 2008, the statute listed only three compendia that CMS could consider: American Medical Association Drug Evaluations (AMA-DE), United States Pharmacopoeia Drug Information for the Health Professional (USP-DI), and American Hospital Formulary Service Drug Information (AHFS), 42 U.S.C. § 1395x.

131. In 1994, the AMA and the U.S Pharmacopeial Convention agreed to combine the AMA-DE and the USP-DI into a single reference; they agreed to use the USP-DI name.

132. In 1998, the USP-DI was sold to Thomson Healthcare, whose Micromedex subsidiary published DrugDex.

133. Under the agreement with Thomson, the U.S Pharmacopeial Convention retained oversight of the USP-DI content until 2004 (when control transferred to Thomson) and Micromedex was responsible for product development, marketing and distribution. Publication of USP-DI ended in 2007.

134. When Part D came into effect in 2006, the statute allowed CMS to rely upon AHFS, USP-DI and DrugDex. 42 C.F.R. § 423.100.

135. Because two of the three original Part B statutory compendia had ceased publication, following its rule-making process, in 2008 CMS added National Comprehensive

Cancer Network Drugs and Biologics Compendium (NCCN), and Clinical Pharmacology to the list of compendia (effective, June 5, and July 2, 2008 respectively) for both Part B and Part D and DrugDex for Part B (effective June 10, 2008).

136. The compendia portion of the Medicaid statute, by contrast, has been stable for the relevant time period.

137. It originally limited the approved compendia to AHFS and the USP-DI. 42 U.S.C. § 1396r-8(g)(1)(B)(i).

138. In 1997, Congress added DrugDex to the approved list of compendia that Medicaid programs could consider. Balanced Budget Agreement of 1997, Pub. L. 105-33 (amending 42 U.S.C. § 1396r-8(g)(1)(B)(i)).

139. Coverage of off-label drug use by TRICARE, the VA and other federal and state healthcare programs is similar to Medicare and Medicaid coverage. *See, e.g.*, TRICARE Policy Manual 6010.54-M, Chapter 8, Section 9.1.

The Anti-Kickback Statute

140. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), which also applies to the state Medicaid programs, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce the referral of business reimbursable under a federal health benefits program.

141. The offense is a felony punishable by fines of up to $100,000 or imprisonment for up to 10 years.

142. In accordance with the AKS, Medicare regulations directly prohibit providers from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals. *See* 42 C.F.R. § 1001.952(f).

143. Such remuneration is a kickback when paid to induce the writing of prescriptions.

144. Kickbacks increase government-funded health benefit program expenses by causing medically unnecessary expenditures.

145. Kickbacks also compromise a physician's judgment causing him/her to consciously or subconsciously select drug regimens based on his/her financial interest rather than the patient's medical need.

146. The AKS defines remuneration to include anything of value, including "cash" and "in-kind" payments or rebates. 42 U.S.C. § 1320a-7b(b)(2).

147. Money and other forms of financial subsidies that can be used to pay or waive Medicare copays constitute remuneration under the AKS.

148. The AKS defines a "Federal health care program" to mean "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," except for the health insurance program for federal employees under 5 U.S.C. §§ 8901 *et seq.* 42 U.S.C. § 1320a-7b(f).

149. As such, the AKS applies to the above government healthcare programs.

150. The AKS further provides that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

151. Under this provision, claims submitted to federal health care programs that result from violations of the AKS are per se false or fraudulent within the meaning of 31 U.S.C. § 3729(a).

152. Accordingly, a person violates the FCA when he or she knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

153. Compliance with the AKS is material to the agency's decision to pay a Medicare claim.

154. The Balanced Budget Act of 1997 added administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. See 42 U.S.C. § 1320a-7a.

155. More recently, the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Medicare Anti-Kickback Statute to specifically allow violations of its "anti-kickback" provisions to be enforced under the False Claims Act.

156. The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of the Social Security Act's anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does not have "actual knowledge" or "specific intent to commit a violation." *Id.* at Sec. 6402(h).

157. Rather, the scienter element of the AKS is established by showing that "one purpose" of the remuneration at issue was to induce referrals, even if the remuneration also had other purposes that were legitimate. *See, e.g.*, *United States v. Kats*, 871 F.2d 105, 108 (9th Cir 1989).

158. Violation of the AKS can also subject the perpetrator to exclusion from

participation in federal health care programs and civil monetary penalties. 42 U.S.C. § 1320a-7(a)(7), (b)(7).

DEFENDANTS' FRAUDULENT SCHEMES

Valeant Knowingly Misbranded and Promoted Drugs for Off-Label Uses

159. Valeant disregarded the FDA approved indications and safety concerns for its drugs and deliberately instructed Relator and other sales representatives to misbrand and promote Valeant drugs for off-label uses.

160. Such drugs include Siliq, Bryhali, Jublia, Duobrii, and Retin-A Micro.

161. Valeant's promotional schemes centered around deceiving and misleading physicians as to the safety and efficacy of drugs rather than a truthful exchange of information.

162. Through Valeant's fraudulent off-label schemes, Valeant caused to be submitted false claims for payment to government healthcare programs and jeopardized patient safety.

Valeant Knowingly Misbranded Siliq

163. Siliq (brodalumab) is a biologic human interleukin-17 receptor A antagonist with only one indication: treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

164. Notably, Siliq, by its very label, is not a first line treatment for moderate to severe plaque psoriasis, but instead requires patients to fail or not respond to other systemic therapies.

165. Plaque psoriasis is a skin disease that causes buildup of dead skin cells on the surface of the skin.

166. This causes inflammation and the appearance of raised, red patches with a white

buildup of dead skin cells or scales on the skin.

167. A key component of the FDA approval of Siliq was the implementation of a Risk Evaluation and Mitigation Strategy ("REMS").

168. Section 505-1 of the Food, Drug, and Cosmetic Act ("FDCA") authorizes the use of a REMS program if the FDA "determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug[.]"

169. A REMS program is a serious regulatory restriction placed on a drug with major safety concerns.

170. Of all of the FDA approved drugs currently on the market, only 58 drugs are subject to a REMS.

171. The Siliq REMS program was implemented by the FDA due to the risk of suicidal ideation and behavior observed during the clinical trials of Siliq, including six completed suicides.

172. Four of the six completed suicides were patients in the psoriasis trial, one suicide was a patient in the rheumatoid arthritis trial, and one suicide was a patient in the psoriatic arthritis study.

173. In the placebo-controlled portion of the trial there were no completed suicides.

174. Due to this major suicide risk associated with Siliq, the FDA also required a black box warning for Siliq which reads:

WARNING: SUICIDAL IDEATION AND BEHAVIOR

See full prescribing information for complete boxed warning.

- **Suicidal ideation and behavior, including completed suicides, have occurred in patients treated with SILIQ.**

- **Prior to prescribing, weigh potential risks and benefits in patients with a history of depression and/or suicidal ideation or behavior.**

- **Patients with new or worsening suicidal thoughts and behavior should be referred to a mental health professional, as appropriate.**

- **Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes.**

- **SILIQ is available only through a restricted program called the SILIQ REMS Program.**

175. Siliq was made exclusively available to patients through the REMS program because of the suicidal risks.

176. That is, a physician could not prescribe Siliq, and a patient could not obtain Siliq, without going through the Siliq REMS program.

177. Every physician, patient, and prescribing pharmacy needs to be certified through the REMS program prior to the writing, filling, and administration of a Siliq prescription.

178. Additionally, Valeant was not able to provide free samples of Siliq due to the REMS program.

179. The FDA's stated goals of the Siliq REMS program are: (1) to ensure "that prescribers are educated about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to counsel patients about this risk[;]" and (2) to ensure "that patients are informed about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to seek medical attention for manifestations of suicidal thoughts and behavior, new onset or worsening depression, anxiety, or other mood changes."

180. Thus, the Siliq REMS program is predicated on a transparent and truthful

exchange of information pertaining to the suicidal risks associated with Siliq from Valeant to the prescribing physician to the ultimate patient.

181. The Siliq REMS program also requires that prescribing physicians become certified prior to prescribing Siliq.

182. The Siliq REMS program also requires that pharmacies become certified before dispensing Siliq.

183. Then, upon certification by the physician, he or she must counsel the patient on the serious risks associated with Siliq, obtain the patient's signature on the Siliq patient-prescriber agreement acknowledging the risks of Siliq, and provide the patient with a Siliq REMS wallet card that the patient must carry with them "at all times."

184. Given these requirements, the REMS program is an intrusive and burdening process that inhibits Valeant's promotion of Siliq.

185. Despite the serious risks associated with Siliq, Valeant engaged in a variety of misbranding and off-label promotional schemes in connection with the sale of Siliq which caused Medicare, Medicaid, and the other healthcare programs cited above, to pay for prescriptions that were off-label and ineligible for reimbursement, and that otherwise would not have been presented for payment to the government programs.

Valeant Unlawfully Promoted Siliq in Violation of the FDA Mandated REMS Program

186. The Siliq REMS program placed an additional hurdle for Valeant in the promotion of the drug because every single prescribing physician needed to be REMS certified prior to prescribing Siliq.

187. Additionally, every patient obtaining Siliq and every pharmacy dispensing Siliq needed to be certified through the REMS program.

188. This certification process, as defined by the FDA in its REMS program goals, requires Valeant sales representatives to ensure all prescribing physicians are educated as to the risk of suicidal ideation associated with Siliq, and are made aware of the suicidal behavior observed in the clinical trials, prior to becoming certified.

189. Given the suicidal risks of Siliq, and the intrusiveness on patients for prescriptions, Siliq is not an easy drug to promote for Valeant.

190. Siliq also carries a price tag of approximately $3,500 per month (and approximately $42,00 annually) for a prescription, which makes every patient, or potential patient, and refilled prescription extremely profitable for Valeant.

191. The high price tag for a Siliq prescription gave Valeant an incentive to certify physicians to write prescriptions for Siliq by disregarding the FDA mandated REMS program and safety concerns.

192. Given the monetary incentive for Valeant, Valeant also sought to have Siliq prescribed as a first line therapy for plaque psoriasis even though Siliq was not approved as a first line treatment.

193. As noted, the Siliq REMS program requires truthful, transparent communication from Valeant to the prescribing physician to the patient regarding the suicidal risks of Siliq.

194. However, rather than ensuring physicians were well educated on the serious risks of Siliq consistent with the REMS requirements, Valeant instructed sales representatives to downplay the risk and mislead the physicians as to the suicidal warning in order to enroll physicians into the REMS program and begin writing prescriptions for Siliq.

195. Once a Valeant sales representative signed a physician up to become REMS certified, any subsequent mention of the suicidal warnings associated with the drug when

promoting Siliq was taboo.

196. As such, Valeant's strategy to promote Siliq was to obtain physician certification into the REMS program by getting around the REMS requirements and black box warning.

197. In January 2018, Valeant flew down Relator and other Siliq sales representatives to Orlando, Florida for a two-and-a-half day "training" on Siliq.

198. Instead of training sales representatives on the suicidal risks that Valeant had a duty to educate physicians on, Valeant trained the sales representatives on how to quickly fill out the REMS forms to enroll prescribing physicians.

199. This was the most important component in Valeant's promotion of Siliq as prescriptions could not begin until physicians were certified into the REMS program.

200. In order to obtain physician certification, Valeant's message for sales representatives at the training was simple: the black box warning and REMS program requirements should essentially be ignored.

201. In fact, Valeant flew down a physician, Dr. Jerry Bagel, who was involved in Siliq studies, and who knew of the suicidal risks associated with Siliq, to Orlando to speak to sales representatives about why the Siliq REMS program and black box warning should not be an issue for sales.

202. Valeant had Dr. Bagel (who also happened to be the sixth highest paid physician by Ortho Dermatologics in 2018) present to sales representatives about why the suicidal warnings were not a big deal and to promote skepticism of the warning from the beginning.

203. Dr. Bagel essentially coached sales representatives on how to downplay and deflect the black box warning for Siliq in order to maximize sales.

204. After training, this message continued to be instilled in Relator and other sales

representatives through group and one-on-one meetings.

205. Valeant instructed sales representatives to gloss over and downplay the suicidal risks associated with Siliq when promoting the drug to a physician and to do whatever it takes to enroll a physician in the REMS program so that prescriptions could start flowing.

206. For example, Relator was told by Valeant management that the black box warning was merely "a smokescreen."

207. Valeant instructed Relator and other sales representatives to, among other things, brush off the suicidal concerns by stating that there were "only four suicides" and was a "small percentage" of all people in the clinical studies.

208. What Valeant did not tell sales representatives was that there were actually six suicides in the clinical studies as highlighted above.

209. Additionally, Valeant instructed sales representatives to tell physicians that the suicides were completely unrelated to Siliq even though no completed suicides were reported in the placebo study.

210. As such, Valeant instructed sales representatives to distort and mislead physicians as to the suicidal risks of Siliq in order to cloud the transparent exchange of information that was required of Valeant under the REMS program.

211. Valeant's promotion of Siliq was built on deceiving and misleading physicians in violation of the REMS program requirements.

212. If a sales representative had difficulty enrolling physicians into the REMS program due to the black box warning, Valeant management would provide solutions on ways to "get around" the warning.

213. The "get around" consisted of various schemes to downplay the suicidal risk to

physicians.

214. As soon as the sales representative enrolled the physician, Valeant instructed the sales representatives to never mention the suicidal warnings to the physician again.

215. Thus, Valeant's promotional scheme of Siliq was to completely undermine the requirements of the REMS program and black box warning by distorting the suicidal risk and misleading physicians.

216. Valeant's instruction to deceive and mislead physicians as to the safety concerns associated with Siliq is in direct violation of the FDA's main goal of the Siliq REMS program: to ensure physicians are well educated as to the risks associated with Siliq.

217. As a result, Valeant knowingly promoted Siliq in a way that violated the FDA mandated REMS requirements and caused to be submitted false claims for payment by federal and state healthcare programs for prescriptions of Siliq that would not have been written had Valeant communicated the suicidal risks of Siliq in the manner required under the FDA mandated REMS program.

Valeant Knowingly Promoted Siliq for Off-Label Uses

218. Siliq carries a narrow indication: plaque psoriasis.

219. Siliq is not indicated for any other conditions.

220. Additionally, Siliq's very indication states that it is only indicated for treatment of moderate to severe plaque psoriasis in adult patients "who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies."

221. In other words, Siliq is not a first line treatment for plaque psoriasis by its very label.

222. In an effort to expand sales of Siliq beyond the label, Valeant pushed sales representatives to promote Siliq as a first line drug for the treatment of plaque psoriasis, as well as for off-label conditions such as psoriatic arthritis.

223. Relator estimates approximately 50% of sales for Siliq were off-label.

224. Valeant's promotion of Siliq for off-label uses was driven in part by an effort to gain market share over competitors.

225. For example, Valeant faces stiff competition among other competitor biologics for plaque psoriasis that carry labels with broader indications than Siliq, such as Humira (AbbVie) which carries indications for rheumatoid arthritis, psoriatic arthritis, and Crohn's disease in addition to plaque psoriasis, Cosentyx (Novartis) which carries indications for psoriatic arthritis and ankylosing spondylitis, and Taltz (Eli Lilly & Co.) which carries indications for psoriatic arthritis and active ankylosing spondylitis.

226. Additionally, even the competitor biologics such as Taltz are not limited by its label to adult patients "who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies," i.e. Taltz may be used as a first line therapy.

227. During training, Valeant educated the sales representatives on the benefits of Siliq for off-label uses.

228. Specifically, Valeant highlighted the alleged benefits of Siliq for patients with psoriatic arthritis.

229. Valeant planted questions from management during training to draw sales representatives' attention to the off-label uses of Siliq and would then follow up with "but you can't say this" to the sales representatives.

230. Relator was confused as to why Valeant would make a point to bring up off-label use discussion during training if Valeant did not want sales representatives to discuss such uses.

231. The goal was simple: Valeant wanted sales representatives trained on off-label uses for Siliq in order to market the drug beyond the one limited FDA approved indication.

232. This goal was furthered by providing sales representatives with white papers containing studies illustrating the benefits of Siliq for patients with psoriatic arthritis in order to bring such uses to a prescribing physician's attention.

233. In addition to the white papers, Valeant also provided sales representatives with cherry picked articles that highlighted the off-label uses for Siliq.

234. Valeant's goal to promote Siliq for psoriatic arthritis was also driven by the fact that competitors had the indication for psoriatic arthritis but Siliq did not.

235. Thus, Valeant wanted physicians to think of Siliq for psoriatic arthritis before writing a competitor drug.

236. In an effort to evade federal off-label regulations, Valeant instructed sales representatives to have physicians submit medical request forms for off-label information on Siliq.

237. Rather than have the request occur organically from the physician, Valeant encouraged the sales representatives to prompt or bait the physician to bring up the topic of off-label use and then have the physician sign the medical request form.

238. Once getting the physician on the topic of off-label uses for Siliq, Relator and other sales representatives were instructed to have the physician fill out a medical request form and a medical liaison from Valeant would then fax over or email off-label information to the physician.

239. Valeant also implemented a speaker program scheme to promote Siliq for off-label uses by enlisting speakers willing to discuss off-label uses.

240. Speakers would routinely answer off-label questions by members of the audience and speak as to their own "clinical experience" or off-label use.

241. As a result, Valeant knowingly promoted Siliq for off-label uses such as psoriatic arthritis and for a first line therapy for plaque psoriasis.

Valeant Knowingly Promoted Bryhali for Off-Label Uses

242. Bryhali (halobetasol propionate) lotion is a topical corticosteroid indicated for the topical treatment of plaque psoriasis in adults.

243. Like Siliq, Bryhali has only one FDA approved indication: treatment of plaque psoriasis.

244. Generally, topical steroids are classified by potency levels ranging from one being the highest potency to seven being the lowest potency.

245. The higher potency steroids tend to pose greater safety concerns with long term use of the drug.

246. Bryhali is classified as a class one steroid with a potent to superpotent potency level.

247. Bryhali is a brand name topical steroid in a market dominated by low cost generic steroids.

248. Given the saturated steroid market with over fifty types of topical steroids, Valeant faced an uphill battle with the promotion of Bryhali against numerous cheaper competitor drugs.

249. Despite the narrow indication of Bryhali, and promotional challenges against

competition, Valeant engaged in a variety of off-label promotional schemes in connection with the marketing of Bryhali which caused Medicare, Medicaid, and the other healthcare programs cited above, to pay for prescriptions that were off-label and ineligible for reimbursement, and that otherwise would not have been presented for payment to the government programs.

Valeant Trained Sales Representatives to Misbrand and Promote Bryhali for Off-Label Uses

250. Sales representatives were trained to deceive physicians about the efficacy and safety of Bryhali.

251. Although Bryhali is a class one steroid with the highest potency among topical steroids, Valeant instructed sales representatives to make false and misleading statements in order to promote Bryhali as a cutting edge, "new class" of steroids unlike the variety of generic topical steroids.

252. Valeant trained sales representatives that Bryhali was a new class of topical steroids that would outperform rival generics.

253. This training focused on the supposed "class three safety" of Bryhali and the drug's "honeycomb structure."

254. At training, Valeant would direct sales representatives to these unsubstantiated claims for Bryhali, and then follow up by telling sales representatives "but you can't say that."

255. In actuality, Valeant wanted sales representatives to be aware and promote Bryhali consistent with these themes to set it apart from the competition and proceeded to routinely remind sales representatives of these concepts through sales managers.

256. Bryhali is a brand name topical steroid in a market driven by generics.

257. As a result, Valeant needed to differentiate Bryhali from the generic competition.

258. One method of differentiation was Valeant's promotion of Bryhali as a drug with

"all the benefits of a class one steroid and all the safety benefits of a class three steroid."

259. Valeant trained Relator and other sales representatives on this misleading selling point for Bryhali despite the fact that it was unsubstantiated with no competent medical evidence establishing that Bryhali in-fact had the safety benefits of a mid-potent topical steroid.

260. With stronger topical steroids, such as Bryhali, long term use could result in safety concerns such as the thinning of the patient's skin.

261. In an effort to sell more Bryhali to more patients (who perhaps couldn't handle a strong topical steroid) and continue that treatment for longer periods of time (a length of time where a class one steroid would be inappropriate), Valeant encouraged sales representatives to present misleading information to physicians as to the safety and efficacy of Bryhali.

262. By promoting Bryhali as a class one steroid with the safety of a class three steroid, Valeant created the illusion to physicians that Bryhali was actually a safe topical steroid that could be used for extended periods of time with minimal side effects, rather a steroid with very high potency.

263. On a national sales call, Valeant had one of the leading sales representatives in the nation talk about his success with Bryhali with all the other sales representatives in the company.

264. The sales representative informed the company on the sales call that Bryhali gives patients all the benefits of a class one steroid with all the safety benefits of a class three steroid—despite the lack of medical evidence that this statement is true.

265. Valeant regional managers used the top sales representative on the national sales call to remind all sales representatives of this unsubstantiated claim to promote Bryhali to

physicians instead of generics.

266. Valeant also provided sales representatives with "slim jims" to give to physicians, which listed all of the potencies of topical steroids and highlighting Bryhali in a class of its own.

267. This marketing piece was used to provide physicians a scale to keep in their pocket of potency levels of steroids and to mislead physicians as to the safety and efficacy of Bryhali over the others.

268. In addition to making unsubstantiated safety claims about Bryhali, Valeant also instructed sales representatives to make unsubstantiated superiority claims over competitor drugs when promoting Bryhali.

269. One way Valeant would promote Bryhali was by training sales representatives on the "honeycomb structure" of the Bryhali chemical makeup, which supposedly resulted in a more effective and safer steroid.

270. Outside of training, Valeant management would regularly bring up the honeycomb structure to sales representatives as a selling point for Bryhali despite the "disclaimer" during training that the sales representatives could not say that term.

271. For example, Relator's manager sent a text message to Relator's Bryhali team stating: "Just heard of reps having some fun w honeycombs and highlighting our vehicle w bringing in a box of honeycombs!!"

272. Thus, Valeant encouraged their sales representatives to bring in props to physicians to highlight Bryhali's unsubstantiated safety and efficacy claims over other drugs to mislead physicians as to the safety and efficacy of Bryhali.

273. Valeant's promotion of Bryhali was built on deception in order to remain relevant in a competitive market of lower cost drugs.

274. In addition to instructing sales representatives to mislead physicians with the "class three safety" of Bryhali or the "honeycomb structure," Valeant also instructed sales representatives to withhold the FDA approved indication when promoting Bryhali.

275. Bryhali has only one indication: plaque psoriasis.

276. In an effort to expand sales beyond the narrow market of plaque psoriasis, Valeant instructed sales representatives to not mention the indication in order to get physicians to prescribe Bryhali for any dermatological condition such as poison ivy or eczema.

277. Topical steroids are commonly used by dermatologists for different skin conditions.

278. With a highly competitive generic market for topical steroids, Valeant relied on promoting Bryhali for other uses that were not FDA approved in order to gain market share.

279. In fact, Relator spoke with a Valeant sales manager who estimated that Bryhali was used 60% of the time for off-label indications and 40% of the time for the drug's indication.

280. Valeant also sought to ensure Bryhali prescriptions were filled over generics for off-label uses.

281. For example, Valeant would instruct sales representatives to tell physicians to write Bryhali prescriptions for off-label uses and to indicate on the prescription that the skin condition appeared to be a mild form of plaque psoriasis instead of what the condition actually was (such as eczema).

282. This would ensure that the brand name prescription for Bryhali was filled for off-label conditions instead of a cheap generic steroid.

283. Valeant also used speaker programs as a means to promote Bryhali for off-label uses by targeting physicians with high topical steroid prescriptions to become speakers for

Bryhali.

284. Valeant also promoted Bryhali to podiatrists.

285. As a result, Valeant knowingly misbranded and promoted Bryhali for off-label uses.

Valeant Knowingly Misbranded Jublia

286. Jublia is an azole antifungal indicated for the topical treatment of onychomycosis of the toenails due to Trichophyton rubrum and Trichophyton mentagrophytes.

287. Jublia is a popular drug for Valeant with Medicare Part D reimbursing over $99 million for Jublia prescriptions from 2014 to 2017.

288. Valeant provided sales representatives with marketing pieces depicting the visual cure of toenail fungus after using Jublia.

289. The complete cure rate—meaning the underlying medical condition was cured—was between 13 and 19 percent for patients on Jublia.

290. However, the visual cure—meaning the toenail fungus visually looked cured—was around 50 percent.

291. Given these figures, Valeant instructed sales representatives to withhold the complete clearance data for Jublia and instead use visual marketing pieces to promote Jublia to physicians by showing that the toenail fungus was visually cleared.

292. Instead of focusing on the actual clearance of the underlying condition, which prescription drugs are actually designed to treat, Valeant emphasized the visual clearance of the underlying condition even though the condition was not actually fully treated.

293. By using this marketing piece, Valeant misbranded Jublia by misleading

physicians as to the efficacy of the drug.

294. Additionally, Valeant instructed Relator and other sales representatives to promote Jublia for the highest quantities possible.

295. For example, Valeant instructed Relator to promote Jublia in the 8ml size, as opposed to the 4ml size, even if the patient did not require that large of a supply.

296. By promoting Jublia for medically unnecessary quantities, Valeant caused the submission of claims to the government health programs for more reimbursement funds than necessary for the patient.

297. As a result, Valeant knowingly misbranded Jublia.

Valeant Knowingly Misbranded Duobrii

298. Duobrii lotion is a combination of halobetasol propionate and tazarotene indicated for the topical treatment of plaque psoriasis in adults.

299. Relator was trained on Duobrii.

300. Like Bryhali, Valeant trained sales representatives on the unique honeycomb formula that differentiated Duobrii and Bryhali from competitors.

301. Valeant then instructed sales representatives to promote Duobrii by emphasizing the unique formula that differentiated it from competitor drugs.

302. As a result, Valeant knowingly misbranded Duobrii by misleading physicians as to the safety and efficacy of the drug.

Valeant Knowingly Promoted Retin-A Micro for Off-Label Uses

303. Retin-A Micro is a retinoid, indicated for topical treatment of acne vulgaris.

304. Despite the single indication for acne, Valeant trained sales representatives on the use of Retin-A Micro for fine lines and wrinkles.

305. Additionally, Valeant launched different strengths of Retin-A Micro upon the lapse of the patent for a certain strength of Retin-A Micro in order to fend off generic drugs.

306. For example, Valeant released Retin-A Micro in a variety of strengths such as 0.04%, 0.06%, 0.08%, and 0.1%.

307. Thus, Valeant instructed sales representatives to promote the newer, branded Retin-A Micro prescriptions to physicians in order to avoid the patient going to a generic drug even if it meant putting the patient on a new strength Retin-A Micro.

308. As a result, Valeant knowingly promoted Retin-A Micro for off-label uses.

Valeant Set Unreasonable Sales Quotas for Sales Representatives

309. Valeant set difficult quotas for sales representatives that were difficult to achieve in order to push sales representatives to promote off-label.

310. For example, with Siliq, Relator estimates that roughly 50% of the Valeant sales force would hit their quarterly quotas for Siliq.

311. Through high, unrealistic sales quotas, Valeant pushed Relator and other sales representatives to promote Valeant drugs off-label.

Valeant Used a "HUB" and a Network of Partnered Pharmacies to Ensure Valeant Prescriptions were Filled

312. A core component of Valeant's promotion of Siliq is to require prescriptions to be sent to a "HUB" called Siliq Solutions.

313. Valeant used the HUB in order to manipulate the government health programs by fronting the initial costs of a patient's Siliq prescription in order to get the patient initially on Siliq.

314. After the patient's initial prescription, Valeant was then able to make the government health programs pay the remaining costs for Siliq prescriptions.

315. Given Siliq's high price tag of approximately $50,000, and lack of indication for first line treatment, government health programs will often reject an initial prescription for Siliq unless the patient has failed to respond to alternative (often cheaper) plaque psoriasis medication.

316. In order to ensure Siliq prescriptions were covered by the government health programs, Valeant instructed sales representatives to make sure all prescriptions for Siliq were sent to the HUB.

317. Once the prescription was sent to the HUB, Valeant would coordinate with a network of partnered pharmacies that guaranteed the patient would receive the prescription for Siliq.

318. As a result, a government health program patient may have his prescription rejected for reimbursement by the government health program initially; however, Valeant would pay the pharmacy the cost for the patient's prescription out-of-pocket in order for the patient to receive the medication.

319. Then, once it came time for a refill, Valeant's HUB would coordinate the refill for the patient by showing a previous history with Siliq, and Medicare and other government health programs would then fill the drug and reimburse subsequent refills.

320. By fronting the initial costs of Siliq, Valeant was able to manipulate the government health programs into paying the vast majority of a very expensive prescription drug.

321. Valeant's initial investment into the first prescription for Siliq was successful as the government health programs would cover subsequent Siliq prescriptions nine out of ten times after the initial prescription paid for by Valeant.

322. Valeant management even told Relator and other sales representatives that Valeant was able to make its initial investment back.

323. By paying for the patient's initial prescription for Siliq, Valeant was able to then recoup its investment through continuous reimbursements by the government health programs for refills of Siliq through the HUB.

324. Because of this, Valeant instructed Relator and other sales representatives to always get prescriptions for Siliq sent to the HUB.

325. Sending a Siliq prescription to the HUB was often a prerequisite to a sales representative obtaining credit for the sale of a Siliq prescription.

326. Additionally, Valeant also instructed sales representatives to steer prescriptions of Bryhali, Duobrii, and Jublia to a network of partnered pharmacies.

327. For example, Relator's manager instructed him and other sales representatives to make sure Bryhali prescriptions were sent to Hebron Pharmacy in Carrollton, Texas even though his territory was in the Virginia, Maryland, and D.C. area.

328. This arrangement was mutually beneficial for Valeant and Hebron (as well as the other partnered pharmacies) as it ensured Valeant prescriptions would be filled and it ensured the pharmacies a continuous stream of business.

329. The steering of Valeant drugs to particular pharmacies ensured that expensive Valeant drugs would be filled that otherwise may be rejected by a normal pharmacy outside of Valeant's network.

330. The pharmacy steering scheme was also used to give Valeant a competitive advantage over the numerous lower cost generic drugs in the same market.

331. Through its partnership with partnered pharmacies, Valeant paid illegal

remuneration to the pharmacies to ensure its prescriptions were filled.

332. As a result, Valeant knowingly caused to be submitted false claims for Siliq, Bryhali, Duobrii, and Jublia prescriptions to the government health programs.

Valeant Used Field Reimbursement Managers to Supply Sales Representatives with HIPPA Protected Patient Information

333. Additionally, Valeant used the HUB to supply its sales force with critical patient data that was protected under HIPAA.

334. For example, Valeant utilized "Field Reimbursement Managers" who were HIPAA certified as a liaison between the HUB, the physicians, and the pharmacies.

335. Valeant then instructed Relator and other sales representatives to contact their Field Reimbursement Manager in order to obtain patient data.

336. With this data, sales representatives were able to find out whether prescriptions for Valeant drugs were filled for a particular patient and the extent of the insurance coverage.

337. For example, once a sales representative knew a particular patient would have the drug covered by a government health program by reviewing the HIPPA protected patient data, the Valeant sales representative would use this information to convince the physician to keep prescribing a particular Valeant drug since it was previously covered.

338. As a result, Valeant sales representatives were supplied HIPPA protected information in order to ensure prescriptions for Valeant drugs were filled.

Valeant Knowingly Paid Kickbacks to Physicians to Influence Prescriptions

339. The federal Medicare Anti-Kickback Statute ("AKS") makes it unlawful to pay remuneration in any form to induce the generation of business reimbursable by Medicare, Medicaid, or any other government-funded insurance program.

340. Despite the AKS, Valeant knowingly engaged in a variety of fraudulent schemes

involving paying kickbacks to physicians to induce prescriptions of Valeant drugs.

341. In order to enable its kickback scheme, Valeant provided sales representatives with an unlimited budget to spend on physicians for lunches, coffee, and other remuneration.

342. In Relator's time at Valeant, he was never told to stop spending.

343. Additionally, Valeant instructed Relator and other sales representatives to spend money on physicians who were writing Valeant prescriptions or had the potential to write Valeant prescriptions, but would forbid Relator and other sales representatives from "wasting" Valeant's money on physicians who were not prescribing Valeant drugs.

344. Valeant also treated its free samples as a commodity of value to influence prescriptions.

345. For example, Valeant instructed sales representatives to give more free samples to its high prescribers and to not provide free samples to physicians who were not writing prescriptions for Valeant drugs.

346. As a result, Valeant drug samples were directly correlated to a physician's prescribing activity.

347. Through a variety of fraudulent kickback schemes, Valeant paid remuneration to physicians to influence prescriptions in violation of the AKS.

Valeant Management Took High Prescribing Physicians out to Lavish Dinners

348. Valeant instructed sales representatives to invite the highest prescribing physicians of Valeant drugs in their territories to dinner with regional sales managers and executives.

349. When the regional managers came to town, Valeant would instruct Relator and other sales representatives to get the top prescribing physicians to agree to go to a dinner with

the regional manager.

350. For example, Relator was instructed by his manager to set up a dinner with Relator's high prescribing physician targets when management came to town in order to reward the high prescribing physicians.

351. Valeant regularly praised the "successful" sales representatives who were able to get the top physicians in their area to go to dinners with management.

352. Valeant management would also take approximately eight high prescribing physicians out to dinner at once when dermatologists met for national or regional meetings.

353. While Valeant imposed a $125 cap per head on dinners for physicians, Valeant management was able to exceed this cap for these dinners with physicians.

354. The restaurants where the dinners were held were not modest by local standards.

355. By wining and dining physicians at expensive restaurants, Valeant rewarded its top prescribing physicians and induced prescriptions of Valeant drugs.

356. Additionally, the president of Ortho Dermatologics, Defendant Humphries, along with regional managers and other Valeant executives, conducted "road shows" where Valeant management would go to various cities and hold events for physicians with food and alcohol.

357. Through the road shows, Valeant management provided remuneration to physicians in order to influence prescription activity.

358. Defendant Humphries' road shows went on for approximately two years.

359. On a national sales call, Relator recalls Valeant management discussing how the road shows worked.

360. For example, Valeant management stated that the road shows resulted in an

increase in Valeant prescriptions for participating physicians.

361. Valeant also held annual events in upscale restaurants for high prescribing physicians that lined up with annual dermatology conferences.

362. Through these wine and dine schemes, Valeant violated the AKS by providing remuneration to physicians to influence prescription activity.

Valeant Used Speaker Programs to Pay Kickbacks to Physicians

363. Valeant's marketing strategy included using speaker programs to pay kickbacks to high prescribing physicians.

364. In order to promote newer drugs on the market such as Siliq, Bryhali, Duobrii, and Onexton, Valeant targeted physicians to participate in its speaker programs who had high prescription volume or potential to become high prescribers of Valeant drugs.

365. Valeant paid speaking physicians between $1,000 and $2,000 for each speaking engagement.

366. Valeant monitored prescription data of speaking physicians to make sure that its investment in the speakers paid off in terms of prescriptions.

367. If a speaking physician was not writing enough Valeant prescriptions, Valeant management, as well as sales representatives, would meet with the physician and mandate that the physician increase his or her prescription volume to obtain more "clinical experience" required to be enlisted on the Valeant speaker programs.

368. If the speaking physician did not increase prescription activity, Valeant would stop using that physician for speaker programs.

369. For example, Relator recalls one instance where Valeant management became upset when a Siliq speaker, Dr. David Cohen, was not writing enough prescriptions and not

discussing based upon his "clinical experience" such as off-label uses.

370. As a result, Relator's management instructed him and other sales representatives to never use Dr. Cohen as a speaker again.

371. Instead, Valeant held speaker events with other physicians who were willing to write prescriptions and discuss off-label.

372. For example, Relator recalls one instance where Valeant held a speaker program in Baltimore with Dr. Neal Bhatia as the speaker even though his medical practice was based in Southern California.

373. Valeant made its top prescribing physicians "thought leaders" and paid them the highest compensation for speaking engagements.

374. Additionally, when seeking to enlist a new speaking physician, Valeant instructed sales representatives to correspond with management entirely orally to avoid any compliance issues.

375. This was a strategic decision by Valeant to hide fraudulent kickback activity in connection with obtaining speaking physicians for Valeant drugs.

376. Valeant also paid its top prescribing physicians and thought leaders to present at Valeant sales meetings.

377. For example, Valeant paid Dr. Leon Kircik (the highest paid physician in 2018 for Ortho Dermatologics with $196,010.50 in general payments) to talk on Siliq at a national sales meeting in San Diego.

378. As a result of Valeant's speaker program schemes, Valeant paid remuneration to physicians in order to influence prescriptions.

Valeant Used Focus Groups to Pay Kickbacks to Physicians

379. In addition to speaker programs, Valeant knowingly used focus groups to provide kickbacks to physicians.

380. Valeant paid physicians compensation, travel expenses, and meal costs to travel to different locations to participate in focus groups about Valeant drugs.

381. At these focus groups, Valeant management would observe discussion from physicians about various prescription drugs to determine what made physicians prescribe a particular drug.

382. Valeant also used these focus groups to promote its drugs to physicians.

383. As a result of the focus groups, physicians receiving kickbacks from Valeant to attend the groups increased their prescriptions for Valeant drugs.

Valeant Retaliated Against Relator for Refusing to Participate in Valeant's Fraudulent Schemes

384. Due to Relator's unwillingness to engage in Valeant's off-label marketing and kickback schemes, Valeant constructively discharged Relator.

385. The False Claims Act contains an anti-retaliation provision that prevents employers from retaliating or otherwise discriminating against employees who engage in protected activity under the statute. *See* 31 U.S.C. § 3730(h).

386. This protected activity not only includes "lawful acts done by the employee" such as filing a False Claims Act case, but also includes "other efforts to stop 1 or more violations of" the False Claims Act. *Id.* at (h)(1).

387. As such, employers may not retaliate against employees who have engaged in investigatory or oppositional activity related to an employer's fraud against the government.

388. Throughout his employment, Relator alerted Valeant management, compliance, and human resources as to specific instances of fraudulent activity by Valeant.

389. For example, Relator complained to his manager that he would not say things off-label when promoting Bryhali.

390. Due to Relator's unwillingness to engage in prohibited practices, Relator was ostracized by his management and forced out of Valeant shortly thereafter.

391. As such, Valeant had knowledge that Relator was raising specific instances in which Valeant was engaging in fraudulent practices against the government.

392. For example, just before Relator left Valeant, he sent an email to Defendants Humphries, Kreider, Webber, and Dubinski stating that his manager "asked [him] to say things off label when promoting [B]ryhali" and that his manager "asked [him] to violate corporate compliance [by] alter[ing] [Valeant] marketing material."

393. Additionally, Relator alerted Defendants Humphries, Kreider, Webber, and Dubinski as to the pharmacy steering and HIPPA issues.

394. As a result, Valeant had knowledge that Relator engaged in protected activity under the False Claims Act and constructively discharged him as a result.

395. Due to Relator engaging in protected activity, Valeant retaliated against Relator resulting in a constructive discharge.

Valeant Caused Claims to be Submitted to and Paid for by the Government Health Care Programs

396. Valeant's fraudulent schemes caused to be submitted false claims for payment to the government health programs identified above.

397. Through Valeant's schemes of illegal kickbacks to physicians and off-label marketing of its drugs, Valeant caused prescriptions of Valeant drugs to be written that were false or fraudulent.

398. Upon information and belief, Valeant caused false claims to be submitted to the

government health programs for Siliq, Bryhali, Jublia, Duobrii, Retin-A Micro, and Onexton that totaled in the tens of millions of dollars related to claims that were tainted by kickbacks or the result of off-label marketing.

399. For example, from 2014 to 2017, approximately $99,661,566.22 was reimbursed by Medicare for Jublia alone.

400. Valeant's illegal kickback and off-label schemes permeated through all areas of the United States.

401. Thus, upon information and belief, Valeant therefore caused false claims to be submitted to the government health programs that totaled in the tens of millions of dollars.

Materiality

402. Valeant's fraudulent conduct induced the government, through its government health plans, to reimburse prescriptions that were caused to be submitted by Valeant as a result of off-label promotion and kickbacks.

403. Valeant's violations of the FDCA through off-label promotion and misbranding of drugs and the AKS through kickbacks were material to the government's payment decision.

404. Through Valeant's off-label promotion and misbranding of Siliq, Bryhali, Jublia, Duobrii, and Retin-A Micro, the government reimbursed costs for prescription of Valeant drugs that were ineligible for government reimbursement.

405. Valeant's off-label promotion and misbranding of drugs was material to the government's decision to reimburse prescriptions for Siliq, Bryhali, Jublia, Duobrii, and Retin-A Micro.

406. No government health program knowingly reimburses prescriptions for off-label prescriptions and, as a result, on-label promotion of prescription drugs for coverage under the

government health programs is material to the government's decision to reimburse prescriptions of those drugs.

407. Had the government known of Valeant's off-label marketing and misbranding of Siliq, Bryhali, Jublia, Duobrii, and Retin-A Micro it would not have reimbursed prescriptions for such drugs.

408. Thus, Valeant's off-label and misbranding violations were material to the government's payment decision.

409. Through Valeant's fraudulent kickback schemes, the government unknowingly reimbursed costs for prescriptions in violation of the AKS.

410. Had the government known of Valeant's unlawful kickbacks, it would not have reimbursed prescriptions for Valeant drugs.

411. Compliance with the AKS is a material condition of payment by government health programs.

412. This materiality is demonstrated by the fact that Congress has determined that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false of fraudulent claim for purposes of [the FCA]." *See* 42 U.S.C. § 1320a-7b(g).

413. Thus, Valeant's kickback violations were material to the government's payment decision.

414. Additionally, Valeant's conduct is material to the government's decision to pay because United States regularly enforces off-label marketing and kickback schemes through the FCA.

415. As a result, Valeant's violations of the FDCA and AKS were material to the government's decision to reimburse prescriptions for Valeant drugs.

COUNT ONE

False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

416. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

417. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

418. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to Medicare, Medicaid, and other Government funded health insurance programs materially false or fraudulent claims for improper payment or approval of prescriptions of Valeant drugs for off-label uses and prescriptions that were tainted by illegal kickbacks.

419. Defendants' conduct was material to the government's payment decision.

420. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

421. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT TWO

False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

422. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

423. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

424. By virtue of the conduct described above, Defendants knowingly caused to be

made or used false records or statements that caused false claims to be paid or approved by the United States.

425. Defendants' conduct was material to the government's payment decision.

426. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

427. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT THREE

False Claims Act, 31 U.S.C. § 3729(a)(1)(C)

428. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

429. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

430. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

431. Defendants' conduct was material to the government's payment decision.

432. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

433. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT FOUR

California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*

434. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

435. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code § 12651(a).

436. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

437. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

438. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the California State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

439. Defendants' conduct was material to the California State Government's payment decision.

440. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

441. By reason of Defendants' acts, the State of California has been damaged, and continues to be damaged, in a substantial amount.

442. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and

every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT FIVE

Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq.*

443. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

444. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*

445. By virtue of the conduct described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

446. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

447. Defendants' conduct was material to the Colorado State Government's payment decision.

448. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

449. By reason of Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

450. Pursuant to Colo. Rev. Stat. § 25.5-4-305(a), the Colorado State Government

is entitled to three times actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record, or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SIX

Connecticut False Claims Act, Conn. Gen. Stat. §§ 4-274 *et seq.*

451. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

452. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 4-275(a).

453. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

454. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

455. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Connecticut State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

456. Defendants' conduct was material to the Connecticut State Government's payment decision.

457. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or

conduct of Defendants as alleged herein.

458. By reason of Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

459. Pursuant to Conn. Gen. Stat. § 4-275(b), the State of Connecticut is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT SEVEN

Delaware False Claims and Reporting Act, Del. Code tit. 6, §§ 1201 *et seq.*

460. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

461. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. Code Tit. 6, § 1201(a).

462. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

463. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

464. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Delaware State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

465. Defendants' conduct was material to the Delaware State Government's payment

decision.

466. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

467. By reason of Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

468. Pursuant to Del. Code Tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT EIGHT

Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*

469. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

470. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.083(2).

471. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

472. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

473. By virtue of the conduct described above, Defendants knowingly conspired with

others to defraud the Florida State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

474. Defendants' conduct was material to the Florida State Government's payment decision.

475. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

476. By reason of Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

477. Pursuant to Fla. Stat. § 68.082(g), the State of Florida is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT NINE

Georgia False Medicaid Claims Act, Ga. Code §§ 49-4-168 *et seq.*

478. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

479. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code § 49-4-168.1(a).

480. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

481. By virtue of the conduct described above, Defendants knowingly made, used, or

caused to be made or used, false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

482. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Georgia State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

483. Defendants' conduct was material to the Georgia State Government's payment decision.

484. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

485. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

486. Pursuant to Ga. Code § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TEN

Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*

487. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

488. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a).

489. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

490. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

491. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Hawaii State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

492. Defendants' conduct was material to the Hawaii State Government's payment decision.

493. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

494. By reason of Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

495. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT ELEVEN

Illinois False Claims Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*

496. Relator re-alleges and incorporates by reference the allegations contained in the

preceding paragraphs as if fully restated herein.

497. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, Ill. Comp. Stat. § 175/3(a).

498. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

499. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

500. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Illinois State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

501. Defendants' conduct was material to the Illinois State Government's payment decision.

502. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

503. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

504. Pursuant to Ill. Comp. Stat. § 175/3(a) the State of Illinois is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWELVE

Indiana False Claims and Whistleblower Protection Act, In. Code §§ 5-11-5.5-1 *et seq.*

505. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

506. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, In. Code § 5-11-5.5-2(b).

507. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

508. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

509. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Indiana State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

510. Defendants' conduct was material to the Indiana State Government's payment decision.

511. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

512. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

513. Pursuant to In. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three

times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT THIRTEEN

Iowa False Claims Act, Iowa Code §§ 685.1 *et seq.*

514. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

515. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code § 685.2(1).

516. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Iowa State Government for payment or approval.

517. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Iowa State Government to approve and pay such false and fraudulent claims.

518. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Iowa State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

519. Defendants' conduct was material to the Iowa State Government's payment decision.

520. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

521. By reason of Defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

522. Pursuant to Iowa Code § 685.2(1), the State of Iowa is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT FOURTEEN

Louisiana Medical Assistance Program Integrity Law, La. Rev. Stat. §§ 46:437.1 *et seq.*

523. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

524. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Program Integrity Law, La. Rev. Stat. § 46:438.3.

525. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

526. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

527. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Louisiana State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

528. Defendants' conduct was material to the Louisiana State Government's payment decision.

529. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

530. By reason of Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

531. Pursuant to La. Rev. Stat. § 438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT FIFTEEN

Maryland False Health Claims Act, Md. Code, Health-Gen. §§ 2-601 *et seq.*

532. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

533. This is a claim for treble damages and civil penalties under the Maryland False Claims Act Against State Health Plans and State Health Programs, Md. Code, Health-Gen. § 2-602(a).

534. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

535. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

536. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Maryland State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

537. Defendants' conduct was material to the Maryland State Government's payment decision.

538. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

539. By reason of Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

540. Pursuant to Md. Code, Health-Gen. § 2-602(b), the State of Maryland is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT SIXTEEN

Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §§ 5A *et seq.*

541. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

542. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Law ch. 12 § 5B.

543. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or

approval.

544. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

545. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Massachusetts State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

546. Defendants' conduct was material to the Massachusetts State Government's payment decision.

547. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

548. By reason of Defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

549. Pursuant to Mass. Gen. Laws ch. 12 § 5B, the State of Massachusetts is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT SEVENTEEN

Michigan Medicaid False Claim Act, Mich. Comp. Laws §§ 400.601 *et seq.*

550. Relator re-alleges and incorporates by reference the allegations contained in the

preceding paragraphs as if fully restated herein.

551. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws § 400.603.

552. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

553. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

554. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Michigan State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

555. Defendants' conduct was material to the Michigan State Government's payment decision.

556. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

557. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

558. Pursuant to Mich. Comp. Laws § 400.612(1), the State of Michigan is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be

made, used or presented by Defendants.

COUNT EIGHTEEN

Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq.*

559. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

560. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. § 15C.02(a).

561. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

562. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

563. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Minnesota State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

564. Defendants' conduct was material to the Minnesota State Government's payment decision.

565. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

566. By reason of Defendants' acts, the State of Minnesota has been damaged, and

continues to be damaged, in a substantial amount.

567. Pursuant to Minn. Stat. § 15C.02(a), the State of Minnesota is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT NINETEEN

Montana False Claims Act, Mont. Code §§ 17-8-401 *et seq.*

568. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

569. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code § 17-8-403(1).

570. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

571. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

572. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Montana State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

573. Defendants' conduct was material to the Montana State Government's payment decision.

574. The Montana State Government, unaware of the falsity of the records,

statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

575. By reason of Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

576. Pursuant to Mont. Code § 17-8-403(1), the State of Montana is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY

Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*

577. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

578. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1).

579. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

580. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

581. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Nevada State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

582. Defendants' conduct was material to the Nevada State Government's payment decision.

583. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

584. By reason of Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

585. Pursuant to Nev. Rev. Stat. § 357.040(2)(a), (c), the State of Nevada is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-ONE

New Hampshire Medicaid Fraud and False Claims Act, N.H. Rev. Stat. §§ 167:58 *et seq.*

586. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

587. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Act, N.H. Rev. Stat. § 167:61-a(I).

588. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

589. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce

the New Hampshire State Government to approve and pay such false and fraudulent claims.

590. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the New Hampshire State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

591. Defendants' conduct was material to the New Hampshire State Government's payment decision.

592. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

593. By reason of Defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount.

594. Pursuant to N.H. Rev. Stat. § 167:61-b, the State of New Hampshire is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-TWO

New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq.*

595. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

596. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-3.

597. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

598. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

599. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the New Jersey State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

600. Defendants' conduct was material to the New Jersey State Government's payment decision.

601. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

602. By reason of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

603. Pursuant to N.J. Stat. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-THREE

New Mexico Medicaid False Claims Act, N.M. Stat. §§ 27-14-1 *et seq.*

604. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

605. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. § 27-14-4.

606. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

607. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

608. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the New Mexico State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

609. Defendants' conduct was material to the New Mexico State Government's payment decision.

610. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

611. By reason of Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

612. Pursuant to N.M. Stat. § 27-14-4, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every

false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-FOUR

New York False Claims Act, N.Y. Fin. Law §§ 187 *et seq.*

613. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

614. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law § 189(1).

615. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

616. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

617. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the New York State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

618. Defendants' conduct was material to the New York State Government's payment decision.

619. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

620. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

621. Pursuant to N.Y. Fin. Law § 189(1)(h), the State of New York is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-FIVE

North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*

622. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

623. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-607(a).

624. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

625. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

626. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the North Carolina State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

627. Defendants' conduct was material to the North Carolina State Government's

payment decision.

628. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

629. By reason of Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

630. Pursuant to N.C. Gen. Stat. § 1-607(a), the State of North Carolina is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-SIX

Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053 *et seq.*

631. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

632. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(B).

633. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

634. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

635. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Oklahoma State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

636. Defendants' conduct was material to the Oklahoma State Government's payment decision.

637. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

638. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

639. Pursuant to Okla. Stat. tit. 6, § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-SEVEN

Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq.*

640. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

641. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(a).

642. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or

approval.

643. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

644. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Rhode Island State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

645. Defendants' conduct was material to the Rhode Island State Government's payment decision.

646. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

647. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

648. Pursuant to R.I. Gen. Laws § 9-1.1-3(a), the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-EIGHT

Tennessee Medicaid False Claims Act, Tenn. Code §§ 71-5-181 *et seq.*

649. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

650. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code § 71-5-182(a).

651. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

652. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

653. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Tennessee State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

654. Defendants' conduct was material to the Tennessee State Government's payment decision.

655. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

656. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

657. Pursuant to Tenn. Code § 71-5-182(a), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT TWENTY-NINE

Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001 *et seq.*

658. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

659. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002.

660. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

661. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

662. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Texas State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

663. Defendants' conduct was material to the Texas State Government's payment decision.

664. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

665. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

666. Pursuant to Tex. Hum. Res. Code § 36.052, the State of Texas is entitled to

three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT THIRTY

Vermont False Claims Act, Vt. Stat. tit. 32, §§ 630 *et seq.*

667. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

668. This is a claim for treble damages and civil penalties under the Vermont False Claims Act, Vt. Stat. tit. 32, § 631(a).

669. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Vermont State Government for payment or approval.

670. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Vermont State Government to approve and pay such false and fraudulent claims.

671. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Vermont State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

672. Defendants' conduct was material to the Vermont State Government's payment decision.

673. The Vermont State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or

conduct of Defendants as alleged herein.

674. By reason of Defendants' acts, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount.

675. Pursuant to Vt. Stat. tit. 32, § 631(b), the State of Vermont is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT THIRTY-ONE

Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1 *et seq.*

676. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

677. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.3(A).

678. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

679. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

680. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Virginia State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

681. Defendants' conduct was material to the Virginia State Government's payment decision.

682. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

683. By reason of Defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in a substantial amount.

684. Pursuant to Va. Code § 8.01-216.3(A), the State of Virginia is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT THIRTY-TWO

Washington Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.005 *et seq.*

685. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

686. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.020(1).

687. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

688. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Washington State Government to approve and pay such false and fraudulent claims.

689. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the Washington State Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

690. Defendants' conduct was material to the Washington State Government's payment decision.

691. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

692. By reason of Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

693. Pursuant to Wash. Rev. Code § 74.66.020(1), the State of Washington is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT THIRTY-THREE

District of Columbia False Claims Act, D.C. Code §§ 2-381.01 *et seq.*

694. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

695. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code § 2-381.02(a).

696. By virtue of the conduct described above, Defendants presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or

approval.

697. By virtue of the conduct described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

698. By virtue of the conduct described above, Defendants knowingly conspired with others to defraud the District of Columbia Government by presenting or causing to be presented false or fraudulent claims for improper payment or approval of prescriptions for Valeant drugs.

699. Defendants' conduct was material to the District of Columbia Government's payment decision.

700. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

701. By reason of Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

702. Pursuant to D.C. Code § 2-381.02(a), the District of Columbia is entitled to three times the amount of actual damages plus the maximum statutory penalty for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by Defendants.

COUNT THIRTY-FOUR

(As to Bausch Health Companies Inc., Bausch Health US, LLC, and Bausch Health Americas, Inc. only)

False Claims Act, 31 U.S.C. § 3730(h)

703. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

704. This claim is a claim for back pay, interest on the back pay, front pay, compensation for special damages, and such other and further relief as the Court may deem proper for injuries Relator sustained as a result of retaliatory actions taken against Relator by Defendants, including litigation costs and reasonable attorneys' fees.

705. Through the acts described above, Relator attempted to stop Valeant from committing violations of 31 U.S.C. §§ 3729 *et seq*.

706. Relator's acts described above, undertaken to stop Valeant from committing violations of 31 U.S.C. §§ 3729 *et seq*., consisted of protected conduct under the False Claims Act.

707. Relator repeatedly raised concerns with Valeant and management that Valeant was engaging in fraud and submitting false claims to the government.

708. Valeant was aware of Relator's protected conduct and acted in retaliation as a result of Relator's protected conduct under the False Claims Act.

709. Through the acts described above, Valeant ignored and/or refused to provide any meaningful response or corrective measures to Relator's lawful inquiries and efforts to address Valeant's ongoing, intentional, and knowing violations of the FCA, the FDCA, and the AKS.

710. As a direct result of Relator's lawful inquiries and efforts to redress Valeant's ongoing, intentional, and knowing violations of the FCA, the FDCA, and the AKS, Valeant retaliated against Relator resulting in his constructive discharge.

711. Valeant is liable under 31 U.S.C. § 3730(h) for (i) an award of double back pay; (ii) interest on back pay; (iii) an award of front pay; (iv) special damages; (v) litigation costs;

(vi) attorneys' fees; and (vii) such other and further relief as the court may deem just and proper.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of herself and the United States Government, the States, and the District of Columbia, requests the following relief:

A. A judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' conduct, plus the maximum civil penalty for each violation of 31 U.S.C. §§ 3729 *et seq.*;

B. A judgment against Defendants in an amount equal to three times the amount of damages the States and the District of Columbia have sustained because of Defendants' conduct, plus the maximum civil penalty for each violation of the State False Claims Acts;

C. That Relator recover all costs of this action, with interest, including the costs to the United States, the States, and the District of Columbia for each of its expenses related to this action;

D. That Relator be awarded all reasonable attorneys' fees in bringing this action;

E. That Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;

F. That in the event the United States Government does not proceed with this action, Relator be awarded an amount for bringing this action of at least 25% but not more than 30% of the proceeds of the action;

G. That a trial by jury be held on all issues so triable;

H. An award of pre-judgment interest;

I. An award to Relator on his retaliation claims including double back pay; interest on back pay; an award of front pay; special damages, litigation costs, attorneys' fees; and

J. Such other relief to Relator and/or the United States of America, the States, and the District of Columbia as this Court may deem just and proper.

PLAINTIFF DEMANDS A JURY TRIAL.

Dated: 12/18/19

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